

**Final Meeting Summary
Organ Transplant Work Group
First Meeting, October 14, 2014
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215**

Work Group Member Attendees:

Charles Alexander

Lori Brigham

Clive Callendar, M.D.

Claudia Donovan, M.D.

David Klassen, M.D.

Linda Ohler

Susan Ostovitz

Jessica Quintilian

Daniel Schwartz, M.D.

Bridget Sullivan

Anne Weiland

Commission Staff Attendees:

Eileen Fleck, Chief Acute Care Policy and Planning

Paul Parker, Director, Health Care Facilities Planning and Development

Other Attendees:

Donna Jacobs, University of Maryland Medical System

Introductions

Ms. Eileen Fleck opened the meeting by introducing herself and asking the members present to introduce themselves. Ms. Fleck noted that Debbie Campbell and Rebecca Goldman, an MHCC staff member, were expected to participate by phone. Due to technical problems, a phone link for the meeting was not established.

Process and Expectations for Work Group

Ms. Fleck thanked members for attending the meeting and noted that she tried to include a variety of perspectives in the group, including hospitals with transplant programs and some payers. She explained that normally MHCC forms a work group to update SHP plans and noted that the SHP chapter for organ transplants has not been updated in over ten years. Typically, such groups meet a few times to discuss and provide their views on key issue to be considered in the Plan update. Staff uses this input to develop draft regulations. The draft may be published for informal public comment before beginning the formal promulgation process. Ms. Fleck explained that she would put together detailed meeting summaries and would not expect the group to create a report with recommendations or agreed upon regulatory language.

Background on Regulation of Organ Transplant Services in Maryland

Ms. Fleck explained that in Maryland, there are some key criteria that are similar across services that include evaluating the need for the service and consideration of the cost-effectiveness of alternatives to a proposed project. She noted that the current State Health Plan includes a minimum volume standard for organ transplantation services, , which is not the case for every service. Also, there is a threshold volume that must be reached before a new program can be considered. A certain amount of unmet need has to be identified before a new program may be considered. There is currently not a need identified for most types of organs that would trigger an opening for review of new organ transplant program development. She noted that the volume standard is one of the issues for discussion by the work group.

Addition of Vascular Composite Allograft Transplants to List of Regulated Organ Transplants

Ms. Fleck noted which types of transplants are covered by the current SHP chapter: solid organs and bone marrow cell transplants. She also noted that vascular composite allograft (“VCA”) transplants are a new addition to federal regulations for organ transplants and specific standards are under development and will likely be revised.¹ Ms. Fleck asked for feedback on how to handle this. Charlie Alexander noted that national guidelines are probably six months away. Mr. Alexander added that trying to create regulations at the state-level that are supposed to hold for 5-7 years may be a bit premature, but at a high level seems appropriate. Ms. Fleck asked the group for its views on how to handle regulation of this new transplant category, specifically asking for clarification if Mr. Alexander was suggesting that it be recognized as a regulated service but without specific, detailed standards within the State Health Plan. Mr. Alexander demurred on the question of CON regulation, because his knowledge is limited to the current status of federal regulatory policy.

Dr. David Klassen noted that he, like Mr. Alexander, is on the national committee developing standards for VCA transplants. He noted that there are two VCA programs in Maryland at The Johns Hopkins Hospital and the University of Maryland Medical Center, and a process is in place for approval of programs through UNOS. He commented that it is too early for standards development. Mr. Alexander noted that only one case has been performed at each of the Maryland programs.

Ms. Fleck asked if the group supported a policy of not approving any new programs. Ms. Weiland proposed “flagging” VCA to review later, such as two years from now. Mr. Parker suggested that the group consider clearly identifying VCA transplants as a category of transplant

¹ In 2011, the Executive Committee of the American Society of Transplantation approved the following description of VCA: “VCA refers to the transplantation of multiple tissues such as muscle, bone, nerve and skin, as a functional unit (e.g. a hand, or face) from a deceased donor to a recipient with a severe injury. These grafts serve as potential replacements for traumatic tissue losses such as limb loss from explosive devices, accidents with farm machinery, burns or other major injuries. VCAs tolerate only limited ischemia time (cannot be processed or stored), require rapid re-establishment of blood flow, and donor-recipient matching, thus sharing identical issues with transplanted organs (governed by UNOS regulations) rather than tissue (for which none of these stipulations apply) and thus have unique characteristics for regulatory purposes.”

falling within the scope of CON regulation in the SHP update under discussion. He noted that there might not be a realistic concern now with respect to proliferation of programs, but it may still be useful to establish a regulatory boundary. Hospitals could be put on notice that we are not ready to consider new proposals because we want to see how the national standards develop. He noted that SHP chapters can be periodically updated more frequently than the five year minimum cycle outlined in law.

Ms. Sullivan asked about the impact for existing programs, if the approach described by Mr. Parker is taken. Ms. Fleck responded that it would not affect existing programs that have already been approved by the Centers for Medicare and Medicaid (“CMS”). She noted that grandfathering programs can occur if a program predates effective implementation of a CON regulatory process. Ms. Fleck asked if the process for getting approval by CMS is a long one.

Mr. Alexander noted that a “high- level” set of standards was put in place by CMS for initial program designation, and a national committee is developing more detailed standards. Dr. Klassen noted that it makes sense to include VCA in the regulations for Maryland. Dr. Claudia Donovan commented that VCA, by nature, is more difficult to characterize and standardize, when compared to solid organ transplantation, because it covers so many disparate types of tissue and procedures. Mr. Parker asked whether it is accurate to characterize the VCA transplant programs at the two Maryland hospitals as programs, given that each has only performed one case, or whether it is more accurate to call them experimental or pilot programs.

Ms. Sullivan responded that she would characterize the Maryland VCA programs as neither programs nor experimental or pilot projects. The VCA programs are at stage between experimental and fully established clinical care. She noted that grant money is available for performing VCA surgeries, and there is a waiting list of VCA candidates. Susan Ostovitz characterized both UMMC and JHH as being at the same level of development.

Ms. Fleck asked the group if there was consensus that MHCC acknowledge in regulations that VCA transplantation is a surgical transplantation service within the scope of CON regulation. Ms. Ostovitz agreed with this approach. Ms. Weiland commented that it might be too early to establish this regulatory status. Ms. Fleck noted that CON regulation is intended to allow only needed programs to be developed to avoid the inherent inefficiencies that could occur through investment in excess program capacity and resources. She noted that if VCA transplantation is excluded from CON regulation, then there should be a solid rationale as to why it does not fall under the term “organ transplant surgery” found in Maryland statute and should not be subject to the same level regulatory oversight that is mandated for other organ and tissue transplantation services.

Dr. Klassen commented that it would be very surprising if there was a rush by many hospitals in Maryland to add the service. The federal government declared that VCAs will be considered organ transplants, so UNOS is responding to that change in the law by developing program standards. It seems to him that it would make sense for Maryland to approach regulation of VCA transplantation in the same way. Mr. Alexander agreed with Dr. Klassen.

Ms. Sullivan asked how specific the language needs to be and whether specific standards need to be developed, such as volume standards. Another member asked if the state would follow what UNOS is doing nationally and then return to the issue later. Ms. Fleck commented that her understanding is that the group believes that developing specific standards at this time is not practical. She also explained that she wanted the group to consider options for handling the issue in the SHP update under consideration for 2015. She noted that one option would be to say that no new VCA programs beyond the two hospitals with federal approval are allowed; another option would be to reference national standards and the federal standards development process, as guidance that will be used if a new program is proposed. Dr. Donovan commented that a hospital already has to obtain permission from UNOS in order to do VCA transplants. Dr. Klassen noted that such approval by UNOS of new VCA transplant programs is limited to existing organ transplant programs.

Mr. Parker stated that he thinks we are at a point where it makes sense to explicitly add VCA transplantation as a category of regulated transplantation services in the SHP. He noted that this is consistent with current Maryland law and regulations that reference organ transplant surgery as a CON regulated service and define organ transplant surgery as “procedures involving the transplantation of organs or tissues, including hematopoietic stem cell transplant procedures.” He proposed that the update explicitly establish that VCA is regulated but acknowledge that standards should be developed after definitive national standards are completed. He also noted that the two existing programs would effectively be grandfathered in. Ms. Fleck suggested that the group move on to the next issue on the agenda, minimum volume requirements.

Minimum Volume Requirements

Ms. Fleck noted that CMS has a standard of ten cases for most types of organs, but does not have a minimum volume requirement for some types, such as pancreas or for pediatric programs. In Maryland, the volume requirement varies by organ type and may be higher than CMS standards. For instance, the minimum volume for kidneys is 30, even though the minimum requirement for CMS is 10. For liver, the requirement is 12, even though the requirement for CMS is 10. She asked for the views of the group on what the minimum volume requirements should be, based on quality concerns, financial feasibility, or other criteria. She noted that CMS may have set its standards low in order to assure access, but she is not sure that is a concern for Maryland. She asked for comments from the group. She also asked whether setting the standard too high should be more of a concern or setting it too low. If the minimum volume standard is very low, then it is, theoretically, easier to justify an additional program. Dr. Klassen commented that the current volume standards seem reasonable, and the existing programs will not have a problem maintaining these volumes. Ms. Fleck asked for confirmation that a minimum of 30 cases annually for kidneys is acceptable.

Ms. Bridget Sullivan noted that it may be important to address pediatric programs in the regulation because there is a children’s hospital that performs only a small volume of transplants. Ms. Fleck asked how the issue of adult versus pediatric transplants is handled by CMS. Dr. Klassen noted that transplantation rates and periods of inactivity by transplant programs are monitored nationally. For kidneys, a program that has not performed any kidney transplants for

three months is flagged. The same is true for livers and hearts. For lungs and pancreas, programs that have not done transplants for six months are flagged. For pediatric programs, if the program has not performed any cases for 12 months, then it is reviewed. He noted that organ acceptance rates are also monitored. Dr. Donovan noted that most minimum transplant volumes refer to adult transplant volumes. However, programs may be adult-only kidney transplant programs, combined adult/pediatric kidney transplant programs, or a pediatric kidney transplant programs. Setting minimum volumes would need to take this into account.

In terms of the regulation of organ transplant services, Mr. Alexander noted that for pediatric programs the selection criteria tend to be more stringent, which also will tend to make the program volume lower. Ms. Fleck asked if a volume standard should be set for pediatric transplant programs or whether it is better to avoid a quantitative standard. Dr. Klassen noted that it would be unusual for a pediatric kidney program to perform 30 cases annually. He also noted that there is not a stand-alone pediatric program in Maryland. However, Ms. Sullivan pointed out that Children's National in Washington, D.C. has a dedicated pediatric kidney program, and it is not likely that Children's National will ever have 30 pediatric kidney transplants in a year. Mr. Alexander commented that he could not come up with a minimum number that would make sense for dedicated pediatric programs. Ms. Lori Brigham asked whether the 50 case threshold standard for kidney programs applies only to Maryland programs. Ms. Fleck responded that the volumes in Washington, D.C. programs are considered in CON regulation of Maryland hospitals, consistent with the policies and standards of the current SHP, even though MHCC has no regulatory authority over D.C. hospitals. Ms. Brigham also asked how compliance with the standard of 50 cases would be evaluated. Ms. Fleck responded that compliance with the standard over time would be relevant, e.g., if volume fluctuated and, in some years, fell below 50 cases but the annual average over several years remained above 50, this would be viewed as substantial compliance.

Dr. Daniel Schwartz commented that we may also want to consider the age of patients for pediatric programs. He noted that sometimes when patients are over age 18, especially patients in need of a heart transplant, a pediatric program which has already performed surgery on the patient may ask CMS if taking the patient is acceptable. Ms. Fleck and another member asked Dr. Schwartz for clarification on the issue. Dr. Schwartz responded that CMS-certified pediatric programs must have more than 50% of their transplants performed on pediatric patients. With low numbers, it may create problems with compliance if they also perform transplants on patients 18 years of age or older. He noted that the distinction between when it is appropriate to treat a patient in an adult program or a pediatric program is not that clear. Ms. Fleck asked how CMS makes those judgments. Dr. Schwartz noted that there has not been a pediatric program out of compliance yet, but sometimes programs have come close to noncompliance and CMS gets questions about the issue. Ms. Fleck confirmed with Dr. Schwartz that for a pediatric transplant program more than half the patients should be pediatric.

Ms. Fleck summarized the commentary of the group on the minimum volume standards noting that the current standards are supported, but the expectations for pediatric programs need to be considered. She noted that no one in the group is proposing specific volume standards for

pediatric programs at this time though. Ms. Fleck asked whether approval should be contingent on national approval through CMS. One member agreed with this idea.

Ms. Brigham asked how that would work, and whether a program would be operating a number of years before getting approved. She asked if MHCC would approve a program contingent on meeting a CMS volume requirement. She noted that a lot of resources go into a program and shutting a program down after a few years may be wasteful. Ms. Fleck agreed that it could be problematic and it would be better to have a specific standard for that reason. Ms. Weiland commented that, unless you speak to it, you are not preventing someone from starting a program, and asked for confirmation on this point. Ms. Fleck commented that it is included in the regulations. Under the current regulations, if a dedicated pediatric program will never be at 30 kidney transplants, then no new program may be added in that region. Ms. Fleck noted that her understanding is that some members of the group see that as a problem, and she is now trying to consider ways to address that issue—to have a different standard for pediatric programs potentially. Ms. Brigham asked about looking at the average case volume nationally. Ms. Fleck agreed that would be a good idea and asked for feedback from other members.

Ms. Sullivan suggested that, as noted in the White Paper, in some states like Kentucky and Illinois, there is not a minimum volume criterion; instead an applicant needs to make a convincing argument for adding a program. She asked whether it is critical to have a defined threshold instead of an open type process where an applicant makes the case. Ms. Fleck agreed that sometimes a more flexible approach may make sense and commented that she could see using that approach for something like the VCAs because they are so specialized and relatively new. However, she noted that it is also helpful to have clear standards so that an applicant knows what to expect before investing a lot of time and money into a process, and it is unclear how the proposal will be evaluated.

Ms. Fleck asked for additional feedback from the group on having a more open process for pediatric programs. Dr. Klassen noted that, typically, hospitals have a pediatric transplant program in conjunction with an adult transplant program. He also noted that there is no specific volume requirement; it's more about having the expertise needed. He did not think it would be possible to set up a minimum volume standard. Dr. Donovan noted that for kidneys it might be possible to pick a small volume standard, but not for any other organs. Mr. Alexander noted that as Ms. Ostovitz said earlier, setting up a stand-alone pediatric program would be prohibitively expensive because it is resource intensive and likely to be low volume. Ms. Fleck asked whether setting up a stand-alone program should be an option at all. Mr. Alexander commented that UNOS does not require pediatric programs to be co-located with an adult program, so allowing someone to make the case for a stand-alone program seems reasonable, even though it seems unlikely that an institution in Maryland would do it.

Minimum Volume Needed to Maintain Financial Viability

Ms. Fleck asked whether anyone could comment on the minimum volume needed to maintain the financial viability of a program. She noted that looking at the financial feasibility of a program is part of evaluating applications for a CON. Ms. Sullivan commented that she is

not sure of the minimum volume needed, but the current volume thresholds are adequate, and more realistic than CMS standards, in terms of maintaining a program. One member commented that it is a costly endeavor, and there are a lot of different factors to consider, such as the patient mix and reimbursement. Ms. Ostovitz noted that other service lines in the hospital may be a factor too. Ms. Sullivan commented that threshold volumes should not be changed based on the response to Ms. Fleck's question and asked if the others who spoke on the issue agreed that the threshold volume should not be changed. They agreed with Ms. Sullivan.

Impact of a New Program on the Volume at Other Programs

Ms. Fleck asked the group how the impact of a new program on existing programs should be evaluated. She asked whether it should be acceptable to add a program as long as existing programs can still meet the minimum standards or if it should be looked at differently, such as the proportion of cases likely to be pulled away if a new program is created. She noted that adding a program would usually mean shifting volume away from existing programs. Ms. Brigham agreed that adding programs will probably just redistribute volume among more programs. With organ transplants, because of the limited number of organs, adding a transplant program won't help to increase volume. Dr. Donovan noted that it could also create problems, such as making it difficult for doctors and staff to keep up their skills, as case volumes are spread more thinly over more program sites.

Ms. Fleck commented that impact should definitely be a concern, but she wants to get more feedback on what level of impact is acceptable. One member commented that it is also important to look at what is happening in the organ procurement Donor Service Areas in terms of trends. For example, is the number of organs increasing over time or decreasing? Mr. Alexander commented that it is not quite that simple. The number of organs is finite, but it would be good to look at what organs are recovered and what organs leave the area in which they are harvested. Every organ recovered in Maryland is not transplanted in Maryland. Mr. Alexander noted that he did not think there is a problem, but the issue should still be examined. Ms. Fleck asked if anyone else wanted to comment.

Ms. Weiland noted that, today, organ supply is a relatively finite resource and that the living donor pool is growing only moderately. Mr. Alexander asked why she thinks that is the case. Ms. Weiland cited multiple reasons, including religious and social beliefs. Ms. Brigham commented that often a lot of people are screened, just to find one person medically suitable; 25 people may be screened just to find one medically suitable donor. Ms. Ostovitz noted that with the paired living donor kidney exchange there has been an increase in living donors. Ms. Sullivan commented that she thinks that there are specific programs at some transplant centers dedicated to increasing the number of living donors and exposing more people to it will increase the number of donors.

Dr. Donovan noted that the problem is that the waiting list is going up exponentially. Ms. Weiland commented that she agreed that demand far exceeds the supply available. Ms. Brigham noted that with changes in national policy, as you consider volume requirements, you need to consider those policies. To some degree, it's unknown what the impact will be, but it is

important to consider in the future. Ms. Fleck agreed and asked if MHCC should be questioning clinical decisions. Ms. Brigham noted that national policy must be followed. Ms. Fleck commented that she understands, but there is some opportunity for discretion by a physician; should that be reviewed? Ms. Brigham noted that she had to throw away 20 lungs in the past year; no one wanted them. It's important to be careful about discounting clinical judgment. Mr. Alexander agreed and noted the focus should be on cases when organ is turned down locally, but transplanted elsewhere. Ms. Brigham agreed that approach makes sense. Ms. Weiland commented that transplant centers have an incentive to do transplants. They do not want to send organs elsewhere. She agrees with respecting clinical judgment and noted that it seems unnecessary to get into that area.

Ms. Fleck suggested that it might be helpful for someone to explain the reasons why an organ might not be transplanted locally and instead get transplanted elsewhere. Dr. Klassen commented if candidates are not available or sick, then organ may go elsewhere. He also commented that for the State to get into figuring out what happened with organs would be complicated, difficult to understand, and not worthwhile. Ms. Weiland added that each surgeon inspects the organ before transplanting it and that's the final clinical approval to ensure the best quality organ for patient survival and graft survival. At the end of the day, it's important to make sure it's functional. Ms. Sullivan agreed, but noted that there are certain protocols at some transplant centers that may affect surgeon's transplants. For example, when JHH was using high risk organs, it had certain testing available for HIV or Hepatitis C. Dr. Callendar also noted that the patient has to agree to take the organ.

Dr. Klassen suggested taking a step back from the idea that organs recovered in Maryland have to be transplanted in Maryland. The idea is to share organs nationally, although there is a hierarchy. He also thinks Maryland may be a net importer of organs. Ms. Sullivan asked Ms. Fleck if she had something in mind when she asked about the appropriate threshold volume for impact on other programs is reasonable. Ms. Fleck suggested that the standard could be that as long as a program is above the minimum, then that's fine. However, you could also consider the relative impact on a program. If a program will lose half its volume, that may not be a good idea because of quality concerns or concerns about the financial feasibility of the program or a major reduction in the cost-effectiveness of the program. She noted that impact can be looked at different ways. Ms. Fleck commented that she has not gotten much feedback on the issue and is surprised by it. She thought some people might feel more protective of their programs. Ms. Weiland commented that outcomes are a concern and that's not addressed in SHP chapter. She suggested that besides volume, looking at outcomes may be an option. Ms. Fleck asked whether she was proposing that the quality of program be considered when looking at impact. Ms. Weiland indicated that she was not endorsing it specifically, just mentioned it as an option.

Dr. Klassen commented that it is important to look at the impact on other programs. There are probably 500 kidney transplants at Maryland hospitals. If that volume was divided by 30, there could be many programs in Maryland, which would not benefit anyone. Ms. Fleck agreed. Ms. Brigham commented that having a threshold volume of 50 might be a bit low for kidneys. She asked whether the question is whether 50 is the right number for kidney programs.

Ms. Fleck commented that there could be different numbers for minimum volume and impact on volume that is acceptable or the volume level that is defined as optimal. She noted that the minimum volume doesn't need to be set at 75 because people think existing program shouldn't go below that volume or some other higher number, as a result of adding a program.

Ms. Ostovitz asked, aren't we putting the cart before the horse? Shouldn't it first be determined if another program is needed? She noted that a lot of resources are needed to start and maintain a good program. The level of the nursing expertise and entire team is not taught in nursing school. It doesn't make sense to allow a hospital to put lots of resources into creating a new program, only to then later shut a program down for not meeting volume requirements. Ms. Fleck agreed that is a key question to ask. She commented that maybe more time should be spent on the question of whether a new program is needed, but it would still be necessary to look at what level of impact is acceptable. Ms. Ostovitz commented that Maryland is a small state with two large programs that are doing a lot of outreach. Ms. Weiland added that there is also a large program in Washington, D.C. and a new one too; in northern Virginia, there is also a new program. She commented that it seems like there is plenty of access for patients in the region. Dr. Donovan agreed with Ms. Weiland's assessment. In the current environment and unless there is a change in the supply of organs, starting a new program would require a large investment which might not be necessary, despite existing programs meeting volume requirements. The need for a new program is not best triggered by the existing programs meeting volume thresholds.

Ms. Fleck agreed that it's difficult to make that determination and suggested that maybe at the next meeting the need projection should be discussed. Ms. Brigham commented that a threshold volume of 50 for kidneys seems very low. Existing programs are doing hundreds. Ms. Fleck commented that MHCC does not consider any a new program based solely on existing programs having a volume above 50 cases. Mr. Parker noted that it is possible to use a real example, livers. Based on the current plan and need projection, there is a region (maybe both regions—Ms. Fleck wasn't sure) where someone could propose adding a liver program. Mr. Parker noted that the relevant numbers are 12 for the minimum program volume and 20 for the threshold volume. Someone asked about the volume of liver programs in the area. It was noted that one is around 120 and another is over 100. Ms. Brigham commented that compared to existing programs, 20 is a very low volume, especially given the resources and the costs associated with creating a new program.

Ms. Fleck said that it sounded like Ms. Brigham is proposing that the minimum volume for a liver program be raised or when a new program should be considered. Ms. Brigham asked whether two liver cases a month is acceptable. Ms. Ostovitz commented that it's not acceptable. Ms. Weiland noted that CMS says that it is acceptable. Ms. Fleck noted that nationally there may be places where access is an issue so it's important to allow for lower volume programs, but she is not hearing that is a concern for Maryland residents. That can be factored in to standards. Ms. Brigham again noted that 20 is a bit low and commented that access is not an issue. Dr. Donovan also noted that the issue is not that a program is overwhelmed, but that the supply of

organs is limited. Ms. Fleck asked whether other people agreed, and if they do, then what number of cases would be more appropriate to set as the minimum.

Mr. Parker commented that he would take a step back. The SHP chapter is simpler than the discussion. Conceptually, the SHP chapter goes through a need methodology for considering a new program. It doesn't automatically give a CON to someone based on the results of the need projection. There is a minimum annual volume requirement, which an applicant needs to show will be met. There is also a threshold volume, which becomes an impact standard in effect. Conceptually, it's not just, do you want to change those numbers? Does the same basic approach make sense for Maryland? Maybe we still want to have a formal need methodology and use different numbers. What else needs to be considered for impact besides the threshold volume?

Dr. Clive Callendar commented that most plans tend not to discuss communities' satisfaction with a program. It's an aspect that could be included. Ms. Fleck asked if anyone else wanted to comment. Ms. Weiland asked how the threshold volume standards were developed in the first place. Mr. Parker responded that he thinks MHCC probably relied on federal standards, and programs were probably smaller than they are now; maybe 50 did not look as low as it does now, when that standard was set. Dr. Donovan commented that the population being served is an East Coast one. It's not South Dakota, where those numbers might be reasonable. Mr. Alexander commented that, if the goal is to align with national standards and create a threshold for not taking requests for a new program, then the goal is probably being accomplished. The threshold numbers allow the start of a conversation. The workgroup might get back to what Dr. Callendar noted about a community articulating a need. Mr. Alexander thinks where we are at makes sense.

Ms. Brigham commented that she thinks the numbers should be reevaluated and she agrees with what Mr. Parker said about looking at the bigger picture and outlining the qualitative arguments that might be made. She commented that it's important to take into account national policy changes and qualitative factors, as also noted by Dr. Callendar. Ms. Weiland asked Dr. Callendar to explain his previous remark and expand on it. Dr. Callendar commented that consumers' perspectives should be considered in addition to morbidity and volume, the same as what is done by every organization and hospital. Ms. Ohler agreed that many factors need to be considered, including volume and availability.

Ms. Fleck agreed and commented that she understands Mr. Parker's point, but the idea of a minimum number of cases is included in other SHP chapters. She also stated that opinions seemed to be mixed on whether MHCC should consider changing some of the minimum volume standards. Ms. Weiland commented that she would like to know what the arguments would be for changing the thresholds. Ms. Fleck commented that there could be efficiency gains with having fewer programs with higher volumes, and the quality of programs may be better with a higher volume program. Those are important considerations. However, she noted that she has not found a source that states kidney transplant programs should ideally perform a specific volume of cases. She also commented that there are national standards, but those standards are not necessarily based on achieving efficiency and optimal quality, which is why it is important to

consider Maryland's particular situation. Ms. Weiland noted that Maryland guidelines are higher than national ones and asked for an explanation of the difference.

A member noted that national guidelines are based on the quality of outcomes. Dr. Donovan commented that UNOS is considering certifying a center for a particular location. A satellite center cannot be tacked on to the same approval; outcomes at a satellite center cannot be hidden. Dr. Klassen agreed with those comments. He noted that in the past, a surgeon could go back and forth between locations, and as a result, patients were underserved in both hospitals. The UNOS' policy proposal states that there must be a specific unique program that is independent. He said that the issue often arises with pediatric programs. Mr. Parker noted that there is an assumption in CON regulations that approval of a transplant program or other services is only for a specific location.

Policy 11, Independent Review of Programs

Ms. Fleck suggested that the group move on to other topics on the agenda. On page 21 in the SHP chapter, Policy 11 states that Maryland transplant programs have to report on programmatic statistics and release information that may be needed to conduct a status review. She read the Policy statement, which notes that a status review should be done by an independent group every three years. Ms. Fleck commented that to her knowledge, status reviews have not been conducted every three years. She asked the group whether it thought that review by the Commission, as described in the policy, is needed. Ms. Brigham commented that it is not just UNOS that reviews programs, it is the Organ Procurement and Transplantation Network. Dr. Klassen agreed that it would be adding a layer of redundancy because there are already specific outcome reports every six months; outcomes are rigorously evaluated. In addition, the reports are publically available. In his view, it would be a waste of time and money for the State to try and duplicate the process. Other members agreed that a review by the State would be redundant.

Performance Metrics

Ms. Fleck asked if there were any performance metrics that should be incorporated into the SHP chapter for organ transplants. She noted that she thought there are few CMS performance measures for programs, and primarily mortality was considered. Ms. Weiland responded that there are many performance metrics. Dr. Donovan and Ms. Ohler agreed. One member noted that there is a score card for adult transplants for each organ type and a separate one for pediatric transplants, measures for the pre-operative steps, measures for living donors, and other standards. She noted that a full-time staff member is needed to assure compliance with reporting on performance measures. One member proposed adopting the performance measures that already exist, and other members agreed. Mr. Parker asked if CMS regularly decertifies programs. Ms. Brigham noted that programs can be flagged for further investigation by CMS. Ms. Ohler commented that in one year she had three reviews, and adding another one would not make sense. Dr. Donovan suggested putting in regulations that a program just needs to be in good standing. Mr. Alexander noted that words should be chosen carefully, because a program that is not in good standing is below probation and other courses of action. Mr. Alexander noted

that the status of a program is reported to CMS. Ms. Brigham commented that maybe the State should be notified too. Mr. Alexander agreed that would be reasonable.

Ms. Fleck asked Mr. Alexander to go over the different labels that UNOS assigns to programs that fall short of performance expectations. Dr. Klassen noted that UNOS has a membership and professional standards committee (“Committee”). He explained that if a program is out of compliance for two reporting cycles in row, then the Committee will look at the program. The Committee could conclude that everything is fine, or issue a letter of reprimand with specific requirements, or issue a notice that the program is a member not in good standing. The latter removes a hospital from participating in the system. He also noted that a program may be put on probation status, and there are many different reasons a hospital may not be in compliance; compliance is not just evaluated based on patient outcomes. Someone asked if the information described by Dr. Klassen gets reported to the State. Dr. Klassen noted that reporting is to UNOS, not the State, but it is a public announcement.

Dr. Schwartz commented that programs do not have to report on results from the Scientific Registry of Transplant Recipients, which is responsible for evaluating all organ transplant programs, because the reports are publically available. Programs are surveyed on a regular basis. Outcome measures are included in the regulations. If a program is out of compliance then a program is issued a prospective Medicare certification termination date. A program can apply for consideration of mitigating factors. If program is out of compliance, usually the state survey agency knows too.

Ms. Fleck commented that it appeared rigorous oversight was in place already and referencing in CON regulations that organ transplant programs should be in good standing seems adequate. Other members of the group agreed. Mr. Parker commented that the SHP chapter for organ transplants includes many policies, including one that states each organ transplant program must comply with all standards for accreditation or certification. He noted that standard could be modified to refer to some of the things discussed. However, Mr. Parker also pointed out that the standard does not matter until someone asks for CON approval to add a new type of organ transplant program. In addition, he commented that a hospital that wanted to establish an organ transplant program would not be subject to those standards because the standards would not be applicable.

Ms. Brigham asked whether a program had to maintain certain standards to keep its CON for an organ transplant program. Mr. Parker noted that CON standards in the current SHP chapter are not really performance standards. He added that, if program is not performing well, there is not much that MHCC can do about it, except for a new program that fails to meet the minimum volume standards. He explained that, when a hospital is awarded a CON, a condition is attached. If the minimum volume standard is not met, then the program would have to voluntarily close its program.

Mr. Parker noted that there has been a shift in the approach to CON regulation of cardiac services recently, and programs that do not meet certain standards are at risk of losing their authority to provide PCI or cardiac surgery services. He noted that the Commission generally is

interested in tying CONs to performance over time, and for this reason, staff wants feedback on whether performance requirements should be included for organ transplant programs.

Ms. Fleck noted that it was almost time to conclude the meeting. She asked if anyone wanted to comment on the issue raised by Mr. Parker or anything else before concluding the meeting. Mr. Alexander commented that anything that can be done to tie performance standards in the CON regulations to existing performance standards makes sense, instead of creating new standards. Mr. Parker noted that with PCI and cardiac surgery services, the standards were set based on standards developed previously by national organizations, such as the Society of Thoracic Surgeons.

Next Meeting

Ms. Fleck asked the group about scheduling the next meeting and the preferred timing. The group seemed to agree that early January is preferred. Ms. Fleck thanked everyone for their time and concluded the meeting shortly after noon.